4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1644]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Conference Attendees' Observations about Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled "Medical Conference Attendees' Observations about Prescription Drug Promotion."

DATES: Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF**

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-N-1644 for "Medical Conference Attendees' Observations about Prescription Drug Promotion." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, Ila.Mizrachi@fda.hhs.gov.

For copies of the questionnaire contact: Office of Prescription Drug Promotion (OPDP) Research Team, DTCResearch@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Conference Attendees' Observations about Prescription Drug Promotion

OMB Control Number 0910-NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. Our research focuses in particular on three main topic areas: (1) advertising features, including content and format; (2) target populations; and (3) research quality. Through the evaluation of advertising features we assess how elements

such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience. Our focus on research quality aims at maximizing the quality of our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first and second topic areas: advertising features and target populations.

Because we recognize the strength of data and the confidence in the robust nature of the findings is improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm. The website includes links to the latest *Federal Register* notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a survey of direct-to-consumer (DTC) advertising conducted in 1999.

The current study focuses on understanding the landscape of healthcare provider (HCP)-directed promotion of prescription drugs at medical conferences in general and, more specifically, how elements of pharmaceutical booths in medical conference exhibit halls impact HCP attendees' perceptions of the drugs that are promoted at those booths. We will first ask attendees, who are prescribers within different disciplines (primary care physicians, specialists, nurse practitioners, and physician assistants), general questions about their attendance at medical

conferences, including: (1) questions about their motivations for attending, (2) activities they participate in (e.g., symposia, poster sessions, social events, exhibit halls), and (3) their opinions about the prescription drug treatments promoted at medical conferences. These questions will allow us to capture the viewpoint of prescribers who attend medical conferences where prescription treatments are discussed and promoted.

The second part of our study will allow us to get more detailed information about interactions in medical conference exhibit halls. A 2006 study found that at least 80 percent of physicians attended at least 1 medical conference each year and spent an average of 7 hours on the exhibit hall floor at each event (Ref. 1). The length of time spent at each booth--between 12 and 21 minutes (Ref. 1)--was comparatively longer than detailing visits in HCP offices, which range from 5 to 10 minutes on average (Refs. 2 and 3). Thus, medical conference exhibit booths provide opportunities for pharmaceutical companies to market to large numbers of HCPs and potentially engage in more lengthy interactions.

Promotional booths for prescription drugs and the promotional materials disseminated at those booths fall within the regulatory purview of OPDP. As with other promotional materials for prescription drugs, pharmaceutical companies may voluntarily submit draft versions of their exhibit panels and exhibit materials for FDA review (Ref. 4). This study is designed to provide insights to inform the advisory comments that OPDP provides to pharmaceutical companies that voluntarily seek FDA review. OPDP also monitors prescription drug promotional booths and materials as part of its surveillance program. Recent compliance letters issued by OPDP described booth or panel displays that communicated misleading information regarding drug efficacy and safety, provided insufficient information on drug risks, and omitted "material facts" about the promoted drug (Ref. 5). A primary reason that physicians and other medical

professionals report visiting specific exhibitors at conferences is to obtain product information (Ref. 1), and it is important that the information provided by exhibitors to HCPs regarding the risks and efficacy of prescription medications not be misleading. Thus, investigating the impact of pharmaceutical booth promotions among medical conference attendees has valuable practical implications for the public health.

As part of our specific exhibit booth research, we will simulate interactions that HCPs may have at medical conference booths promoting prescription drugs, so that FDA can examine the effects of the booth representative's background (scientist/medical professional versus business professional) and disclosure of data limitations (present versus absent). In a recent survey, HCP conference attendees reported that interacting with company representatives was the most important element of their booth visits, followed by the availability and quality of clinical information (Ref. 4). Thus, the perceived credibility of the booth representative and the availability of information on data limitations could ultimately inform HCPs' perceptions of the risks and benefits of drugs presented at exhibit booths and their decisions to prescribe drugs to patients.

Indeed, literature suggests that credibility and disclosures are relevant elements to study in the context of prescription drug conference booths. Credibility is linked to extrinsic (physical attractiveness, power) and intrinsic (delivery factors, linguistic cues) factors. For example, one extrinsic feature of source credibility is similarity between the source and recipient. Research on the effects of source similarity has been mixed, but a classic field experiment by Brock in 1965 found that customers buying paint were more likely to follow recommendations of a salesperson they perceived as having painting experiences similar to their own (Ref. 6). More recent studies have examined the effects of endorsers with professional expertise versus those with product

experience on attitudes toward the brand and promotion (Refs. 7 and 8). These past studies are relevant to our manipulations of booth representative background in this study given that representatives with a medical/science background may reflect professional expertise, whereas representatives with a business background may reflect product experience.

There is little empirical evidence on the impact of disclosing data limitations during promotional detailing or other sales promotion. On one hand, providing important information (e.g., key limitations) about the data/drug should help increase comprehension and decrease inaccurate or unjustified interpretations of the data. On the other hand, seeing the disclosure of data limitations--essentially tempering the study findings and providing a sort of two-sided information that is not necessarily in favor of the drug's effects--may improve the material's credibility and appeal by signifying more transparency on the sponsor's part (Ref. 9), and therefore lead to greater interest in the drug (regardless of accurate comprehension). Conversely, not seeing any qualifying or clarifying information could raise red flags among providers, resulting in the lowest levels of perceived credibility. Whether the booth representative has a medical/science background or business background may shape perceptions of credibility even further, thereby influencing HCPs' perceptions of the drug. Thus, while disclosure of data limitations and credibility of the booth representative may have independent effects on HCPs' comprehension and perceptions, these variables could also interact in their effects.

I. Research Questions

With this background in mind, we plan to address the issue of how firms communicate about prescription drugs from the perspective of medical conference/exhibit hall attendees. Specifically, we will ask for attendees' general observations of:

1. disclosures or disclaimers accompanying exhibit hall presentations and/or symposia (about data limitations, contrary data, FDA approval status, financial/affiliation sponsorship, etc.);
2. publications or references accompanying the presentation of information (PI for approved indications, contrary data references, etc.);
3. what type of studies are being reported (real world evidence, pharmacokinetic/pharmacodynamic studies, meta-analyses, etc.).
4. who makes the presentations (field of study, training); and
5. where the presentations are made (poster session, scientific floor, exhibit hall).

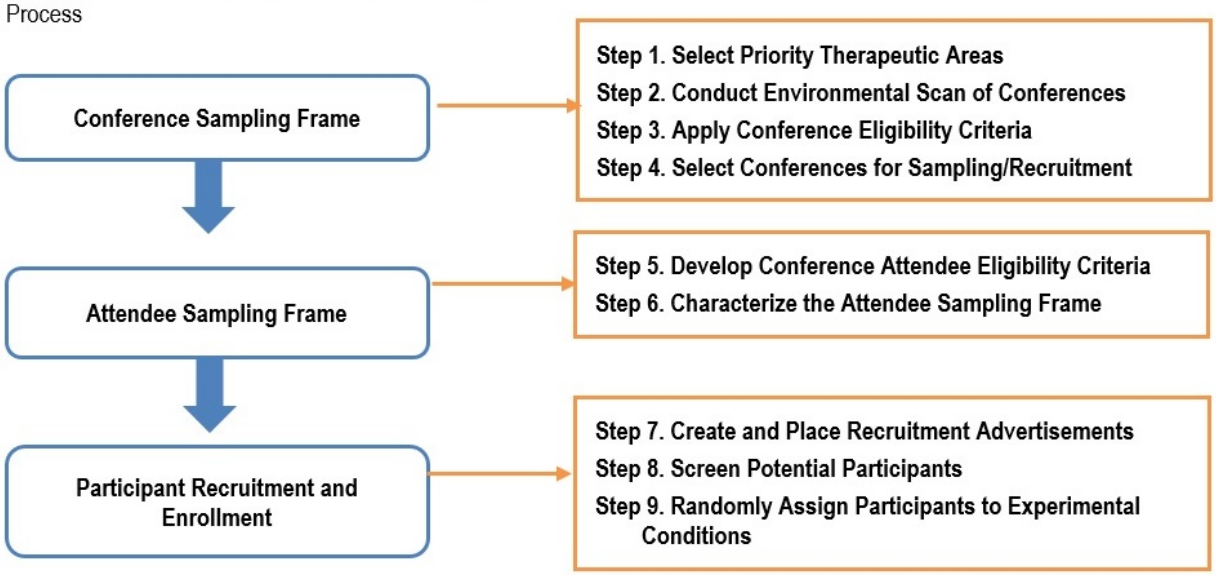
We will also address exhibit hall pharmaceutical booth interactions, specifically:

1. How does the presence or absence of information about the limitations of data influence perceptions of the promoted product?
2. How does the background of the booth representative influence perceptions of the promoted product?
3. Do these two variables interact?

II. Method

To complete this research, we will recruit attendees of large medical conferences in the United States over the course of 1 year. These conferences will represent a variety of specialties to reflect medical areas that have prescription treatments that may be promoted to HCPs. Specifically, we will enroll HCPs who attended one of 12 selected medical conferences into an online survey within 7 days of conference attendance. Exhibit 1 summarizes our approach to: (1) determining the conference sampling frame; (2) determining the attendee sampling frame; and (3) recruiting and enrolling the target sample in the online survey.

Exhibit 1. Sampling Frame and Participant Recruitment Process



In the first step, we will select conferences that focused on therapeutic areas that have the following attributes:

- high number of currently promoted branded medications;
- high volume of prescriptions written;
- large patient population; and
- high amount of new drug development and promotional spending.

Table 1 shows the final criterion for conference inclusion. Conferences that meet these criteria will be selected based on an environmental scan.

Table 1.--Conference Eligibility Criteria

Criterion	Parameters
Therapeutic area	Associated with one of the prioritized therapeutic areas
Conference attendance	Estimated attendance of 5,000 or more individuals
Target audience	Focused on prescribers and clinicians (e.g., not insurers)
Event date	Scheduled during August 2021--August 2022
Event location	Domestic (within United States)

Following conference selection, medical conference attendees at each conference will be randomly selected, invited to participate, and screened to ensure they are HCPs with prescribing authority who responded to the survey invitation within 7 days of attending the target conference. HCPs will be limited to physicians, nurse practitioners, and physician assistants who spend 20 percent or more time in direct patient care, are able to read and speak English, are not currently employed by the Federal government or a pharmaceutical company (not including occasional consulting), and have not participated in another wave of the project.

The online survey will be broken into two main parts: (1) a cross-sectional survey designed to capture HCP observations from the medical conference and (2) an experimental study designed to assess how data disclosures and exhibit booth representative background influence HCP perceptions of promoted prescription drugs. The cross-sectional part of the survey will contain a series of close- and open-ended questions. The experimental study part of the survey will ask participants to view a brief video simulating a conference exhibit hall interaction between an HCP attendee and a booth employee and then answer questions about a fictitious prescription drug featured in the video. Table 2 shows our proposed study design and sample size across 12 conferences.

Table 2.--Study Design and Target Sample Sizes

Disclosure	Booth Employee Background		Total
	Business	Medical	
Present	n = 92	n = 92	184
Absent	n = 92	n = 92	184
Total	184	184	368

FDA estimates the burden of this collection of information as follows:

Table 3.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Screener	933	1	933	.08 (5 minutes)	74.64
Pretest	25	1	25	0.33 (20 minutes)	8.25
Main test	368	1	368	0.33 (20 minutes)	121.44
Total					204.33

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Mack, J. (March 2006). "Effective Physician Marketing at Medical Meeting Exhibits." *Pharma Marketing News, 5(3)*.

2. *Industry Standard Report (2014). "Pharmaceutical Detailing: In-Person vs. Electronic vs. Phone." Retrieved from https://www.isrreports.com/wp-content/uploads/2014/08/ISR-Pharmaceutical-Detailing-In-Person-vs.-Electronic-vs.-Phone-Preview-Aug2014.pdf.

3. Steinman, M. A., G. M. Harper, M. M. Chren, et al (April 2007). "Characteristics and Impact of Drug Detailing for Gabapentin." *PLoS Med, 4*(4), e134. http://dx.doi.org/10.1371/journal.pmed.0040134.

4. Adler, D., A. Sherman, and M. Walz (2017). "Medical Conference Presence: Is it Worth it for Your Brand?" Retrieved from https://www.pharmavoice.com/article/2017-9-medical-conferences/.

5. *FDA. Warning letters and notice of violation letters to pharmaceutical companies. Retrieved from https://www.fda.gov/drugs/enforcement-activities-fda/warning-letters-and-notice-violation-letters-pharmaceutical-companies.

6. Brock, T. C. (June 1965). "Communicator-Recipient Similarity and Decision Change." *Journal of Personality & Social Psychology, 1*, 650-654.

7. Braunsberger, K. and J. M. Munch (1998). "Source Expertise Versus Experience Effects in Hospital Advertising." *Journal of Services Marketing, 12*(1), 23–38.

8. Siemens, J. C., S. Smith, D. Fisher, and T. D. Jensen, (2008). "Product Expertise Versus Professional Expertise: Congruency Between an Endorser's Chosen Profession and the Endorsed Product." *Journal of Targeting, Measurement and Analysis for Marketing, 16*(3), 159-168.

9. Pechmann, C. (1992). "Predicting When Two-Sided Ads Will be More Effective Than One-Sided Ads: The Role of Correlational and Correspondent Inferences." *Journal of Marketing Research, 29*(4), 441–453.

Dated: September 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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